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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,711	02/22/2002	Ramanan Ramaswami	Ramaswami-1	1247

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/081,711	Applicant(s) RAMASWAMI ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this c mmunicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *12 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-22,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Acknowledgement of Papers Received: Amendment and Response dated 4/10/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-11, 13 – 22, 24 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Medford et al (USPN 5,380,747) in view of Acharya (USPN 5,102,666) and Chen (USPN 6,180,606). The claims are drawn to a device, which delivers vasodilating agents where the formulation comprises the agents and a biocompatible carrier. The carrier is biodegradable, and is recited to be methylcellulose or equine collagen. The agents are selected from well-known vasodilators such as nitroglycerine, and verapamil. Claims 13 – 22 are drawn to a method of delivering vasodilating agents using the device of the agent.

As discussed previously Medford discloses a composition comprising biodegradable polymers and vasodilators useful in treating atherosclerosis. Medford et al teaches a treatment for cardiovascular tissues, where a device comprising a carrier and a vasodilating agent is applied to tissue in need (col. 4, lin., 33 – 45). The agents are discloses as calcium channel blockers such as verapamil, diltiazem, and nifedipine (col. 4, lin. 55 – 60; col. 15, lin. 45 – 53;

col. 16, lin. 18 – 21). The carrier for the device is disclosed as a biodegradable polymer. The reference also suggests that the composition be implantable.

What is lacking however is a disclosure of nitroglycerin as a vasodilator, and methylcellulose as the biodegradable polymer. Acharya discloses a treatment for wound healing and drug delivery comprising administration of a biodegradable polymer such as methylcellulose and medicaments including vasodilating agents like nitroglycerin (col. 2, lin. 24 – 40; col. 4, lin. 52 – 58; col. 6, lin. 56 – 68). The device of Acharya can be implanted through injection or direct implantation. The device once in the body swells and polymerizes. The device then slowly releases the medicaments over time. A skilled artisan would have been motivated to combine the polymers and vasodilators of Acharya with the device of Medford in order to deliver various vasodilators to any site in the body.

With regard to the concentrations of the vasodilating agents in the carrier, the references all disclose the general combination of a topical formulation of a vasodilating agent with a biocompatible carrier. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various topical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to the recitation of the equine collagen, it is the position of the examiner that such a limitation is merely the selection of an equivalent species, which would be obvious to one of ordinary skill in the art. As seen in Chen, which discloses the use of collagen as a biocompatible carrier composition, equine, human, bovine, and porcine or ovine collagen can be used and interchanged for the purposes of carrying an active agent (Abstract; Examples, claim 40). It is the position of the examiner that due to the knowledge in the art as to the equivalency of these collagen sources for the purposes of active agent carrying, the selection of equine collagen does not impart patentability to the invention barring a showing of criticality to that particular source along with unexpected results of the choice.

Also with regard to the size limitations applicant is reminded that the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984)).

With these aspects in mind, one of ordinary skill in the art would have been motivated to combine the teaching of Acharya and Medford. The formulation of Acharya would allow the fit anywhere in the body including a graft site, since it is injectable and polymerizes once in the body, form fitting to its surroundings. Acharya also discloses applications directly to the site as opposed to injectable embodiments. These devices would be as equally biodegradable A skilled artisan would have been motivated to interchange the biocompatible polymers of the two teachings in order to maximize and optimize the release of the particular vasodilating agent. The

final form of the device is well within the level of skill in the art to modify. A skilled artisan would be able to produce patches or injectable implants from the references presented. A skilled artisan also would have been motivated to provide a treatment comprising the delivery of vasodilating agents in biodegradable carriers. A skilled artisan would have been motivated by Medford to treat cardiovascular tissue, and Acharya to treat wound healing sites. The devices of the combination would be applicable in any site in the body including a graft site, where much wound healing occurs. The patches could be perforated for easier dissemination, but this too would be within the level of skill in the art to obtain and determine. It would have been obvious to a skilled artisan to combine the teachings and suggestions in the art with an expected result of a biodegradable delivery system able to fit anywhere in the body.

Response to Arguments

4. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
June 30, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600